EXHIBIT C

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL NO. 1456 CIVIL ACTION: 01-CV-12257-PBS Subcategory Docket: 06-CV-11337-PBS
THIS DOCUMENT RELATES TO *U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al.*, No. 06-CV-11337-PBS	)	Judge Patti B. Saris Magistrate Judge Marianne B. Bowler

DECLARATION OF JAMES W. HUGHES

I, James W. Hughes, hereby depose and state as follows:

1. I am over the age of 18. I have personal knowledge of, and am competent to testify about, the matters set forth herein.

2. I have been retained by the Defendant Abbott Laboratories Inc. to serve as an expert witness, offering expert opinion testimony, in the above-captioned matter. I am submitting this Declaration in support of Abbott Laboratories Inc.'s Motion *in Limine* To Preclude Certain Opinions Proffered by Plaintiffs' Expert Mark G. Duggan, Ph.D.

3. Attached hereto is a true and correct copy of the Expert Report of James W. Hughes, dated March 6, 2009, that I prepared in connection with my engagement:

4. If called to testify at trial, I would testify in a manner consistent with the opinions expressed in this expert report.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on 6/25, 2009 in Waterville, Maine.

James W. Hughes

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL NO. 1456 Civil Action No. 1-12257-PBS
THIS DOCUMENT RELATES TO: *United State of America ex rel. Ven-a-Care of the Florida Keys, Inc., v. Abbott Laboratories, Inc.*	)	MASTER FILE NO. Judge Patti B. Saris

EXPERT REPORT OF JAMES W. HUGHES

I. Introduction

1. I am the Thomas Sowell Professor of Economics at Bates College. I prepared this report at the request of counsel for Abbott Laboratories Inc. ("Abbott") to review and evaluate the Government's liability and damage calculation in this matter as proposed by its expert Dr. Mark Duggan.

2. In my opinion Dr. Duggan's calculation of damages is fatally flawed in both concept and execution. First, as he admits, his is not a damage calculation, but only a calculation of a "difference" in government expenditures. His concept of the but-for world does not consider the evidence in the record of the likely consequences were state and federal agencies to adopt the alternative payment methodologies he proposes. He ignores, for example, the testimony of state officials and other evidence that reimbursements like the ones he proposes would require increases in dispensing or administration fees. He ignores the fact that when the government reformed the Medicare and Medicaid systems to address the issues that are the subject of this litigation, the reforms adopted bear no resemblance to his alternative payment method. A valid vision of the but-for world should take into account the likely consequences for, and reactions by, market participants. Dr. Duggan's does not do this in my opinion.

3. Even if one were to accept Dr. Duggan's but-for world, his method of calculating damages is in my opinion fatally flawed. For Medicare, his estimates are based on a small amount of variable data that is in no manner a random or representative sample of the data. From these flawed data, he performs extrapolations across time and space that have no statistical validity. Even though Abbott did not account for 100 percent of the sales in the data he uses in his calculations, and even though he has no idea whether

Abbott's alleged wrongful actions were in fact the cause of injury in his extrapolations, he attributes 100 percent of the damages he calculates to Abbott.

4. For Medicaid, he bases his national damage estimates on incomplete claims data on only ten states. The ten states he chose are not a representative sample of the population of states. He ignores data on other states that is in his possession, or presumably available from the government. He uses extrapolation to estimate damages to 38 other states, introducing needless error into his estimates. For these and other reasons, the resulting estimates are in my opinion inaccurate and unreliable. Dr. Duggan also fails to consider the consequences of his proposed reimbursement method on patient access. He ignores substantial evidence showing that concern over inadequate dispensing fees and the potential effects on patient access was, in fact, a major factor in shaping states reimbursement policies.

5. By using flawed, incomplete unrepresentative data, and using these data to calculate extrapolations that are flawed and unrepresentative of the but-for world, it is my opinion that Dr. Duggan's damage methodology and resulting estimates are inaccurate and unreliable.

II. Background and Experience

6. I specialize in the fields of Industrial Organization; Law and Economics; Health Economics; Environmental Economics; and Labor Economics. I earned my M.A. in Economics, from Boston University in 1978, and my PhD in Economics from The University of Michigan in 1987. I joined the faculty of Amherst College in 1987 and the faculty of Bates College in 1992. In 2005, I was named the Thomas Sowell Professor of Economics.

7. I have experience in the economic analysis of competition issues in the pharmaceutical industry, including injury and damage issues in the AWP litigation. I submitted a report in an AWP action regarding certain injectable drugs brought by the Attorney General of Connecticut[1]. I also submitted a report in the AWP actions in the states of Montana and Nevada[2]. Outside of the AWP actions, I have testified and/or offered reports in matters involving the prescription pharmaceuticals Cipro, Cardizem, Rezulin and Procardia XL. I have also testified in a class certification matter involving the prescription benefit manager Medco Health Systems. My curriculum vita is attached as Exhibit 1, and a list of cases in which I have provided testimony appears as Exhibit 2.

III. Basic Allegations and My Assignment

8. The Government alleges that Abbott reported "false, fraudulent and inflated"[3] prices to the pricing compendia such as the Red Book. The Government further claims that such allegedly false reporting caused agencies to pay "excessive"[4] reimbursements to Abbott's customers.

9. The Government also claims that Abbott consciously manipulated the so-called "spread" between the AWP (used in computing some government reimbursements) and the price actually paid by Abbott customers. This alleged manipulation operated by either indirectly raising the AWP, or lowering the customer's purchase price, or both,

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[1] State of Connecticut v. Aventis Pharmaceuticals, Docket X07 CV03-0083299 S (CLD).
[2] In Re Pharmaceutical Industry Average Wholesale Price Litigation, in the matters of: *State of Nevada v. American Home Prods. Corp., et al.,* 02-CV-12086-PBS; and *State of Montana v. Abbott Labs., Inc., et al.,* 02-CV-12084-PBS, MDL NO. 1456, Master File No. 01-CV-12257-PBS.
[3] In Re Pharmaceutical Industry Average Wholesale Price Litigation, The United States' First Amended Complaint, Civil Action No. 01-12257-PBS, at ¶3. [Hereafter cited as "Complaint"]
[4] Id. at ¶3

thus increasing the customer's profit, not Abbott's profit, from the transaction. According to the complaint, Abbott allegedly profited from this "scheme" by increasing sales of its products.[5]

10. I have been asked by counsel for defendant Abbott to evaluate the Government's liability theory and damage claims. I have been asked to review the methodology employed by the Government's expert for estimating the injury, damages, and penalties allegedly incurred by Medicare and Medicaid as a result of the alleged wrongful actions, and to offer my opinion as an economist about the opinions, methodology and accuracy of the resulting estimates. A list of materials I relied upon is attached as Exhibit 3. I am being compensated at a rate of $575 per hour.

IV. Factual Background

A. Nature of the Products at Issue

11. Pharmaceuticals are generally classified as either "brand-name" (i.e., patent-protected) drugs, or "generic," also referred to as multisource drugs.[6] Most of the products at issue in this litigation fit in neither the brand nor generic categories. Most of the products here are legacy hospital products that have never been patent-protected. These are basic, commodity products—saline solution, sterile water, dextrose solution—that have been used in hospitals and elsewhere for decades. Many companies have long manufactured such solutions. Any company meeting the FDA standards for sterility, purity and manufacturing practice can produce such products. As these solutions are

[5] Id. at ¶3, 103

[6] One of the subject drugs of this litigation, vancomycin, is an example of a generic multisource drug.

uncomplicated, barriers to entry are low by the standards of pharmaceutical markets. Today, there are up to 15 manufacturers for these products.[7]

12. Legacy hospital products are commodity products. Each firm's products are functionally and literally identical to the products of every other manufacturer. Markets for such commodity products tend to be quite competitive. As such, day-to-day prices change with the forces of supply and demand. If one or more manufacturers face supply issues, prices in the market may rise in response. Unforeseen emergencies such as natural disasters can lead to increases in demand and price. Products may be sold to different customers at different prices depending on market and demand circumstances.

B. The Use of List Prices

13. Firms in many different industries use list prices as both actual transaction prices and a starting point for negotiations with larger customers, regular customers, and/or new customers whose business they are trying to win. Such a practice allows firms to charge the list price to "spot" customers, who may buy either small quantities of the product, or on a one-time basis. Larger, regular customers or buying groups can negotiate lower prices, the size of the discounts correlating generally with the importance of the customer. Price discounting in this way helps firms compete for business by rewarding their best customers, and/or attracting new customers with lower purchase prices. Multiple products may be grouped together and sold as a portfolio of products.[8] Generally, customers who purchase all or substantially all of the portfolio of products can receive more favorable pricing and terms.

[7] Electronic Orange Book, accessed online at www.fda.gov/cder/ob/docs/queryai.
[8] Deposition of Michael Sellers, March 31, 2008, v. II at 594.

14. It is well established in the economics literature that monopolistic collusion is facilitated when firms can observe each other's actual selling prices.[9] Competitive price-cutting is, on the other hand, greatly encouraged when, as in this case, firms can keep their discounting practices confidential. A leading text on competitive strategy, discussing how competitors might facilitate price collusion, states:

> When sales transactions are "public," deviations from cooperative pricing are easier to detect than when prices are secret. … [I]n many industrial goods markets, prices are privately negotiated between buyers and sellers, so it may be difficult for a firm to learn whether a competitor has cut its price. Because retaliation can occur more quickly when prices are public than when they are secret, price cutting to steal market share is likely to be less attractive, enhancing the chances that cooperative pricing can be sustained.

When sellers can keep their sales prices confidential, competition is enhanced:

> Secrecy is a significant problem [for colluders] when transactions involve other dimensions besides a list or invoice price, as they often do in business-to-business marketing settings. … [A] manufacturer…that wants to steal business from a competitor…can cut its "net price" by increasing trade allowances to retailers or by extending more favorable credit terms. Because it is often more difficult to monitor trade allowance deals or credit terms than list prices, competitors may find it difficult to detect business-stealing behavior, hindering their ability to retaliate.[10]

15. In short, offering discounts from list price to gain and keep customers is more successful when the discounts are kept confidential than when they are done publicly. Publicly announced reductions in selling price may be quickly matched by competitors, making them an ineffective method for gaining or keeping customers. Publicly

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[9] The antitrust economics literature is replete with schemes would-be colluders have employed to force disclosure of transaction prices. Reporting prices to trade associations, basing-point pricing and the like are recognized as classic methods of facilitating collusion through the use of published transaction prices.

[10] David Besanko, David Dranove, and Mark Shanley, *The Economics of Strategy,* 2d ed., (New York, John Wiley & Sons, 2000) at 305-306.

announced discounts are more costly to producers as the firm's other customers will demand similar discounts. As lower prices for manufacturers' products ultimately benefits consumers, economists believe that such discounting should be encouraged rather than discouraged.

16. Professor Fiona Scott-Morton examined the effect on drug prices of the Medicaid "Most-Favored Customer" (MFC) requirement contained in the Omnibus Budget Reconciliation Act of 1990 (OBRA 90).[11] An MFC clause requires that all customers must receive the lowest price given to any one customer. An MFC clause is thus identical in effect to the public disclosure of pricing discounts, as any discount must be applied to all covered customers. Professor Scott-Morton found that drug selling prices actually rose somewhat after the passage of OBRA 90. Discounting became more expensive for firms, and firms thus did less of it. She also found that the dispersion of selling prices became less, again indicating less discounting. Professor Scott-Morton concluded that the MFC requirements of OBRA 90 actually caused the prices paid by some pharmaceutical customers to rise.[12]

17. Abbott's former Hospital Products Division published a list price. This list price was the price at which Abbott sold directly to a provider who did not have a negotiated contract,[13] that is, it was the price for spot purchases.[14] For repeat customers and larger

[11] Fiona Scott-Morton, "The Strategic Response by Pharmaceutical Firms to the Medicaid Most-Favored-Customer Rules," Rand Journal of Economics, v.28 n. 2, Summer, 1997 at 269-90, and "The Interaction between a Most-Favored-Customer Clause and Price Dispersion: an Empirical Examination of the Medicaid Rebate Rules of 1990," Journal of Economics and Management Strategy, v.6 n. 1, Spring 1997 at 151-174.
[12] Scott-Morton, Rand Journal at 269.
[13] Deposition of Michael Sellers, March 16, 2008 v. 1 at 245.
[14] On May 1, 2004, Abbott sold its Hospital Products Division.

customers, Abbott offered contracts whereby such customers could purchase products from Abbott at a price less than the list price. These discounts were offered, and at times increased, both to meet competition for existing customers and/or to win new business.[15] Abbott's profit or loss on such contract sales did not depend on whether the providers using its products would be reimbursed by Medicare Part A (hospital care), Medicare Part B (physician care), Medicaid, private insurance, or cash payment. Abbott's profit or loss would depend only on the price paid to Abbott by the customer and the quantity sold at that price.

18. It is important to understand that Abbott sold its products directly or indirectly (i.e., through a wholesaler or distributor) to providers (e.g. hospitals, pharmacies, dialysis centers, outpatient surgery centers, home infusion pharmacies), and was paid by providers for these products. Providers then dispensed or administered these products to patients. Third-party payers, Medicare or Medicaid, or the patients' cash payments reimbursed providers for these patient services. Third party payer reimbursements were made to the providers, not to Abbott.[16] The Government claims that Abbott profited from the alleged AWP manipulation scheme by increasing its sales.[17] Dr. Duggan's report presents no evidence to support this allegation.

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[15] Abbott's contracts with customers generally contained clauses requiring Abbott to match any competitor's offered price for the products in the contract. See, for example, Corum Healthcare Contract, at ABT-DOJ 0205106.

[16] Abbott operated three home infusion pharmacies in California, New Jersey and Illinois at various times between 1984 and 1999. Sellers Deposition at 481. These pharmacies received reimbursements from Medicaid. Dr. Duggan calculates that total Medicare and Medicaid spending through Abbott's home infusion pharmacies totaled only $380,499 over the period 1992-1999. Duggan Supplemental Report , p. 3.

[17] Complaint at p. 1, ¶¶3, 75-77, 103, and 146.

19. Abbott announced list price changes annually for its hospital products. Because of the competitive nature of the market for these products, these changes were generally limited to no more than the relevant rate of inflation. As such, these price changes were not real (after inflation) price increases, but rather consistent with inflation. Exhibit 4 shows the time trend of price for the NDCs at issue in this litigation, graphed against the Consumer Price Index for Medical Products.

V. Dr. Duggan's Damages Calculations Are Inaccurate And Unreliable As They Are Based On A Fanciful and Untenable Vision of the But-For World

20. When estimating damages, an economist compares the price actually paid with the price that would have been paid in the "but-for" world, that is, the world absent the defendant's alleged wrongful behavior.[18] Any valid vision of this but-for world must be based on the available evidence as to the situation that would actually exist in the world without the alleged wrongdoing. This evidence must include not only the alleged but-for price, but also include an assessment of actors' anticipated responses to the incentives, rewards, and costs imposed by the changed circumstances. To do otherwise will result in an inaccurate and misestimated "but-for price" that will yield inaccurate and unreliable estimates of alleged damages.

21. Dr. Duggan does not conduct such an economic analysis. His characterization of the but-for world is one-dimensional, divorced from the realities of the market he purports to analyze. He calculates a "difference between (1) what the federal government reimbursed for certain pharmaceutical products provided to Medicaid and Medicare recipients during the eleven-year period 1991 to 2001 and (2) what the federal

[18] See Roger Blair and William Page, "Speculative Antitrust Damages," 70 Wash. L. Rev., April 1995.

government would have reimbursed for the same products during the same time period of prices reflective of the actual prices at which Abbott was transacting business had been used for the AWP, WAC, and Direct Price of Abbott products."[19] He then assumes that Medicare and Medicaid reimbursements would have been reduced to the payment levels utilized in his "difference" calculation.[20] Everything else, including provider participation in the programs, dispensing or administration fees paid to compensate providers for the cost of preparing, delivering and administering the drug and other factors are assumed to remain constant. Other influences, such as the need to meet Federal mandates to ensure access in the Medicaid program, the information available to government officials, or the presence of MACs, or other reimbursement methodologies willingly negotiated between providers and state Medicaid agencies are not taken into account in Dr. Duggan's analysis. All of these factors would be an integral part of any viable and accurate economic assessment of alleged damages.

22. As I will discuss in more detail below, by ignoring these very real economic factors in his analysis, Dr. Duggan's calculations do not constitute a damage analysis in this matter. Notably, he himself never uses the word "damage" in his entire initial report in this matter,[21] and resists characterizing his calculation as "damages" caused by Abbott's alleged misconduct at deposition,[22] preferring instead to refer to his calculations as merely a "difference" in government payments between the actual and his but-for

[19] Report of Mark G. Duggan, Ph.D., June 19, 2008 at ¶1.
[20] Id. at 8-9.
[21] Id.
[22] Deposition of Mark G. Duggan, PhD., vol I, July 15, 2008 at 37:13-47:21 and 76:20-79:6.

world.[23] He says that his calculations are merely "one input into the calculation of damages."[24] Dr. Duggan ignores a vast amount of evidence and testimony in this matter that speaks directly to the accuracy of his characterization of the but-for world. Dr. Duggan admits that he uses assumptions in his analysis that he has not verified.[25] He does not use all of the actual claims data in his possession, nor did the government provide to him other claims data that the Government presumably has in its possession. Instead, his alleged damage estimates are based on extrapolations that are themselves flawed. He ignores the fact that, almost fifteen years after the filing of this matter, after many successful and unsuccessful attempts to reform drug reimbursements under Medicare and Medicaid, no state or Federal program has replaced the reimbursement system at issue here with a system with the same or similar characteristics to the one proposed by Dr. Duggan. He ignores the fact that, even today, CMS continues to approve state Medicaid implementation plans containing the same allegedly flawed reimbursement system that gave rise to the current litigation.[26]

A. Medicare

1. Dr. Duggan's But-For World Is Inconsistent With Government Reforms Of The Medicare Reimbursement System

[23] While Dr. Duggan uses the term "difference" rather than "damage" to describe his calculations, it is my understanding that the Government is using his calculations as their estimate of damages in this matter. For this reason, I refer to Dr. Duggan's calculations as damage or alleged damage calculations.
[24] Id. at 39.
[25] Duggan Deposition at 28-29, 86-88, 193-96, 674-82, and 858-65.
[26] According to the CMS website, all but two states' reimbursement systems are based on AWP in some way. U.S. Health and Human Services, Centers for Medicare and Medicaid, "Medicaid Prescription Reimbursement Information by State—Quarter Ending December, 2008," accessed online at http://www.cms.hhs.gov/Reimbursement/Downloads/MedicaidPrescriptionReimbursementInformationbyStateDecember2008.pdf.

23. During the relevant period for this litigation, Medicare reimbursed at either 100 percent or 95 percent of AWP. In the case of multisource drugs produced by many manufacturers, like the ones at issue in this litigation, Medicare paid 95 or 100 percent of the median AWP for the product, plus in some cases an administration fee.[27] In Dr. Duggan's but-for world, if Abbott alone had reported the average acquisition cost of its products, he claims that the median AWP, and therefore the Medicare reimbursement would fall. Administration fees would not have changed according to Dr. Duggan, despite the need for trained professionals to store, prepare, deliver and administer these injectable and infusion products.

24. The Medicare reimbursement system in place during the relevant time period was replaced by a new system specified in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003[28], known as the "MMA." If Dr. Duggan's characterization of the but-for world is in fact accurate, we should expect the payment system of the MMA, constructed in response to the alleged shortcomings of the earlier system at issue here[29], to closely mimic the but-for payment system proposed by Dr. Duggan. It does not.

25. Under the new MMA system, the drug reimbursement for most drugs would be set at 106 percent of the average sales price (ASP) of the manufacturer,[30] calculated

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[27] In 1999, reimbursement was changed to 95% of the median AWP or the lowest brand AWP, if a brand product existed.

[28] "Medicare Prescription Drug, Improvement, and Modernization Act of 2003," CMS Legislative Summary, April, 2004, accessed at: http://www.cms.hhs.gov/MMAUpdate/downloads/PL108-173summary.pdf.

[29] "Medicare and its beneficiaries are making excessive payments for prescription drugs. The published AWPs that are currently being used for Medicare-contracted carriers bear little resemblance to actual wholesale prices that are available to the physician and supplier communities that bill for those drugs." U.S. HHS Office of Inspector General, "Excessive Medicare Payments for Prescription Drugs," December, 1997 at ii.

[30] Id. at p.48.

according to a specific formula contained in the statute. However, the statute recognized that the administration fees, where applicable, of the earlier system would be inadequate to compensate providers for the cost of the drug preparation, delivery and administration services. Thus, in direct contradiction of Dr. Duggan's characterization of the but-for world, where administration costs are assumed to be constant, the new legislation called for a substantial increase in these drug administration costs. These new costs were to be based on survey information from providers regarding the actual cost of providing such services.[31] On top of this resource-based adjustment, the MMA required an additional 32 percent increase in the administration fees for 2004, and another three percent in 2005 to facilitate the transition.[32] Congress mandated that Medicare drug reimbursements could not be so drastically reduced without a substantial increase in administration fees. Dr. Duggan completely ignores this fact, an omission that, in my opinion, invalidates his damages methodology.

26. Importantly for the current matter, infusion drugs administered using durable medical equipment (DME) were exempted from the reduction in reimbursement that would result from the new payment method. Vancomycin, a drug at issue in this matter, fits into this category during the relevant time period. Congress mandated that these drugs were to continue to be reimbursed at 95 percent of AWP (as published by the pricing compendia), exactly the methodology that Dr. Duggan claims would be abandoned.[33] Dr. Duggan ignores this fact in constructing his but-for world.

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[31] Id. at p. 49-50

[32] Id. at p. 50.

[33] "Infusion drugs furnished through an item of covered durable medical equipment would be paid at 95 percent of the October 1, 2003 AWP until such drugs were under the competitive bidding system for durable medical equipment." Id. at 48. One subject drug,

27. Exhibit 5 shows examples of the effect of applying the real-world MMA alternative reimbursements on Dr. Duggan's calculations for J-codes 7040 and 7060, rather than the fanciful and unrealistic but-for reimbursements he employs.

28. When the Medicare drug reimbursement system was overhauled in 2003 by an act of Congress, after years of analysis and public criticism regarding the alleged shortcomings of the extant reimbursement system, the system adopted bore little resemblance to that posited by Dr. Duggan. Where reimbursements were reduced, drug administration fees were raised to compensate providers for the costs of preparing, delivering and administering these products. For drugs like one of the drugs at issue here, the former system was deliberately maintained. Because of the demonstrated disconnect between Dr. Duggan's but-for world, and the actual reforms to the system adopted by Congress, I conclude that any calculations based on such a misapprehension of the but-for world are inaccurate and unreliable.

2. It Is Impossible For Abbott To Enrich Itself Under The Medicare System By Manipulating AWP As Alleged

29. When reimbursing multisource drugs like the ones at issue in this litigation, Medicare adopted a policy of reimbursing at 95 percent of the "median AWP" of the drug, regardless of which manufacturer's product was dispensed. Because the carriers

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vancomycin, is no longer covered under Medicare Part B DME benefit. However, former HCFA Administrator Scully testified that vancomycin is in the class of drug that would be exempted were it still paid under Medicare. Deposition of Thomas A. Scully, May 15, 2007, v. I at 361-362. A large proportion of the vancomycin claims were administered through DME.

and DMERCs did not use consistent methods to calculate this median, reimbursements were neither common nor consistent across carriers or across time.[34]

30. Medicare carriers would form "arrays" of drug AWPs from the pricing compendia (Red Book). Even the small number of arrays used by Dr. Duggan indicate a lack of accuracy, consistency, and uniformity.[35] First, the number of products in the array and the NDCs[36] chosen for the array were ad hoc. Carriers would choose different numbers of products and different NDCs both across carriers and over time. [37] As a result, it is not clear that any Abbott NDCs would in fact be used in any carrier's array at any point in time. If Abbott's AWP does not appear in a particular array, Abbott's AWP could have no effect on the level of the reimbursement. Second, carriers would include products of different package sizes in a single array. Placing the wrong package sizes or drug strengths in an array could cause the median AWP, and thus the reimbursement, to be higher or lower than warranted by the package size or strength called for in the particular J-code.[38]

31. With such unsystematic and ad hoc construction of arrays across carriers and across time, it would have been impossible for Abbott to manipulate its AWP so as to increase its own profits. Abbott could not have known if its NDCs were in any particular array, if so, which of its NDCs were in the array, which other producers' NDCs were in

[34] OIG Report, "Excessive Medicare Payments…" supra. note 34 at 9, Duggan Report, at 83-95.
[35] Duggan Report, at 81-82.
[36] The acronym NDC stands for National Drug Code, a numerical code that uniquely identifies a manufacturer, drug product, dosage and package size.
[37] See, for example, Exhibit 6.
[38] See, for example, Exhibit 7.

the array, and the AWPs of those products. Without such information, Abbott could not possibly manipulate AWP in such a way so as to alter the median AWP to its advantage.

32. More telling is the fact that, regardless of the information available, Abbott could not increase its profit through manipulation of its AWP under the Medicare program. Any increase in Medicare payments due to the alleged AWP manipulation would accrue to providers, and not to Abbott. Increases in Medicare reimbursements to providers could not provide any competitive benefit to Abbott as all manufacturers' products were reimbursed at the same rate. According to the Government complaint, Abbott allegedly profited by increasing its sales of its products.[39]

33. Given the structure of the Medicare reimbursement system, it would be impossible for Abbott or any other company to move sales to itself by manipulating its AWP. Under the Medicare system, providers received the same reimbursement regardless of which manufacturer's product was dispensed. Even if Abbott's alleged AWP manipulation caused the median AWP to increase, the increased reimbursement would be paid on all manufacturers' products, not just on Abbott's. As the reimbursement to providers is the same regardless of which manufacturer's product is dispensed, no provider would have the incentive to switch to Abbott's products even if Abbott's pricing led to an increase in the Medicare reimbursement. No amount of alleged AWP manipulation could increase Abbott's sales through the Medicare system. No amount of alleged AWP manipulation could increase Abbott's profit through the Medicare system.

[39] See note 17 supra.

34. I conclude that Dr. Duggan's basis for calculating damages is based on a flawed vision of the but-for world. He calculates Medicare damages based on a theory of wrongful behavior that Abbott had neither the ability nor the incentive to engage in. He bases his damage estimates on a vision of the but-for world containing an alternate reimbursement method that is at odds with the methods actually adopted under the Medicare program. Ignoring the realities of the Medicare system leads Dr. Duggan to estimates of damages that are inaccurate and unreliable.

3. Dr. Duggan's Damage Calculations Under Medicare Are Arbitrary And Speculative

35. Even if one were to accept the but-for world of Dr. Duggan's Medicare damage calculations, which I do not, the implementation of his method is fatally flawed. As I noted above, the Medicare reimbursements were based on the median AWP for the J-Code regardless of manufacturer. These medians were derived from arrays that were themselves flawed due to the lack of a standard methodology across time and carrier, changing product inclusion and the inclusion of assorted product sizes and strengths.

36. Dr. Duggan compounds these existing problems by calculating out of sample extrapolations that completely lack any statistical basis or other foundation. First, Dr. Duggan relies on actual arrays from carriers[40] that cover only about five percent of the relevant time periods for each carrier and J-code, of this action as shown in Exhibit 8. Second, the arrays he uses are in no way a random sample of carriers' arrays. Rather, it

[40] Medicare contracts out its claim processing work to private firms known as "carriers." These carriers are often insurance companies like Blue Cross/Blue Shield. There were 28 such carriers around the country in 1997. Arrays were supposed to be updated quarterly, and there were 44 quarters over the 11-year period of this litigation. In principle, there should be one array per carrier, per J-code for each of the 44 quarters covered by this claim.

is my understanding that he relies solely on the arrays that were provided by the Government. In such a sample of convenience, there is no reason to believe that the arrays used are in any way representative of arrays used by other carriers, at other times, for other J-codes, or throughout the eleven–year time period. Extrapolations from such a nonrandom, arbitrary sample of arrays have no statistical validity, and are doubtless inaccurate and unreliable. I have no confidence that a different ad hoc sample of arrays would not result in an entirely different damage calculation.

37. With such a limited sample of convenience, without any indication of whether Abbott NDCs were used in or influenced the median of the missing arrays, Dr. Duggan's damage estimates are nothing more than speculation. He speculates, but neither knows nor demonstrates, that Abbott NDCs, the correct Abbott NDCs, are in every array for every carrier at every point in time. He speculates, but neither knows nor demonstrates, that it is the AWP for an Abbott NDC that causes the movement in the median and consequent reimbursement. He speculates, but neither knows nor demonstrates that the available array for one carrier at one point in time is identical to all other carriers' arrays at that point in time. The available arrays show this assumption to be baseless, as carriers' arrays vary greatly at a single point in time. He speculates, but neither knows nor demonstrates that the array for a given carrier in a given period is the same for that carrier for all other periods where he does not have an array. Again, Dr. Duggan's own evidence shows this assumption to be without basis, as individual carriers' arrays vary across time. Any extrapolation from such a slipshod sample to other carriers or periods of time is baseless and without merit.

38. Further evidence of the fanciful and unrealistic nature of Dr. Duggan's alleged damage estimates is shown by his attribution to Abbott of 100 percent of the alleged damages to the Medicare system from the drugs at issue in this matter. Despite his repeated claims that his damage estimates are "conservative," it is difficult to imagine how Dr. Duggan could consider such baseless and counterfactual choices to be conservative. Abbott competed for business with more than ten other manufacturers of these products. Abbott never accounted for 100 percent of sales during any time period or in any geographical region. Dr. Duggan offers no evidence to the contrary. Dr. Duggan offers no evidence that Abbott was the only manufacturer whose compendium AWP was greater than its average selling price, and would therefore be the only AWP to be adjusted in his but-for world. Nevertheless, in Dr. Duggan's but-for world, Abbott is the only manufacturer whose price reporting was to change. Dr. Duggan assumes that Abbott's AWP moved the median AWP in each and every array at every point in time, without offering any evidence that Abbott NDCs were even contained in all of the arrays. Far from being conservative in his choices, Dr. Duggan in this case has made choices that have the effect, in my opinion, of overstating Abbott's alleged damages by attributing 100 percent of damages to Abbott when such a conclusion is clearly at odds with the facts.

39. Dr. Duggan's damage estimates for the Medicare program are hopelessly compromised as they are based on a but-for world that is flatly contradicted by the available evidence, and use a methodology that is speculative, overreaching, and lacking in any scientific validity.

B. Medicaid

40. As is the case with Medicare, Dr. Duggan's damage estimates for Medicaid are tainted by reliance on a but-for world that is at odds with the record in this matter. For Medicaid, Dr. Duggan's but-for world relies on the following assumptions: First, it assumes that state and federal officials were unaware for the entire relevant period that AWP did not constitute a selling price and WAC did not include discounts and rebates. Second, it assumes that, had officials been aware of these pricing realities, they would have not only changed reimbursement policy immediately, but also that they would have based Medicaid reimbursements on his calculation of average acquisition cost. Third, Dr. Duggan assumes in the but-for world that dispensing fees would not increase to compensate for the loss in revenue to providers from the reduction in reimbursement; Fourth, his but-for world assumes that all states are the same, that they face the same challenges in ensuring access to care, and all states respond in the same way to such challenges and obstacles. Clearly, this is not the case, as illustrated by the fact that Medicaid implementation plans are designed and approved on a state-by-state basis. As I will show in the following pages, all of these assumptions are at odds with the record in this matter. By ignoring these factors in constructing his but-for world, Dr. Duggan has in my opinion greatly overstated the likely damages resulting from the alleged wrongful behavior in this case.

1. What Information Did Medicaid Officials Have About Pharmaceutical Pricing Practices?

41. An accurate assessment of the but-for world is essential to a valid damages analysis. What information government officials had about pharmaceutical prices and when they had it is highly relevant to characterizing the but-for world. AWP has never been equal to average acquisition price. Dr. Duggan's damage assessment assumes the

government never knew this fact over the past forty plus years. If, conversely, many or most government officials were fully aware that AWP does not equal average acquisition cost, and formed their reimbursement systems in full cognizance of that fact, a very different but-for world and very different damage assessment would result.

42. Evidence will be presented at trial as to what government officials knew or did not know about pharmaceutical pricing practices and how these affected reimbursements. The facts and testimony cited below are the result of my nonexhaustive review of the record. I understand that the record is replete with other similar facts. The point is that whatever the facts turn out to be from trial testimony, they are relevant to the accurate assessment of damages, yet Dr. Duggan has ignored such factors in his damage calculation.

a. Government Reports

43. A long history of reports both by, and commissioned by, government agencies, testimony before Congress and legislatures, filings in legal challenges and other public actions shows that government officials at all levels had considerable information available to them that AWP was not a selling price and that WAC did not include discounts and rebates. This history now stretches back over 40 years.

44. In 1968, the U.S. Department of Health, Education and Welfare (HEW) published a report on prescription drugs.[41] The task force noted,

> …wholesalers, retailers, hospitals and government agencies often pay markedly different prices for the same drug and dosage form.[42]

[41] U.S. Department of Health, Education and Welfare, "Task Force on Prescription Drugs: The Drug Makers and Drug Distributors," U.S. Government Printing Office, 1968.
[42] Id. at 31

and,

> The *Red Book* and Blue Book do not reflect actual manufacturers' prices to wholesalers and retailers which are determined by the amounts of various kinds of discounts.[43]
>
> The catalog [list] price constitutes an 'umbrella' beneath which the company can maneuver against competing products.[44]

45. In 1974, an HEW Federal Register Notice read

> Red Book data, Blue Book data (i.e. AWP) and other standard prices…were frequently in excess of actual acquisition cost.[45]

46. A 1977 HCFA action memo to states noted that

> [T]he Department is not convinced that those states which continue to reimburse at average wholesale price or wholesale invoice cost have made a real effort to approach actual acquisition cost.[46]

47. In 1984, a report from the Office of the Inspector General for the Department of Health and Human Services found that pharmacies purchased most drugs at an average price 15.9 percent below AWP,[47] while actual prices were as much as 42 percent below AWP. The report noted that AWP was not "…even an adequate estimate of the prices providers are generally paying for their drugs. AWP represents a list price and does not reflect several types of discounts."[48]

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[43] Id.
[44] Id. at 33
[45] U.S. DHEW, "Proposed Reimbursement of Drug Cost," 39 Fed. Reg. 230 at 41,480, November 27, 1974.
[46] HCFA Action Transmittal 77-113 (MMB) ""—Formula for Determining EAC for Drugs at ¶28,714.
[47] HCFA Action Transmittal, No. 84-12, September, 1984, "Medicaid—Limitation of Payment for Drugs" at ¶34,157 p. 10,193.
[48] Id. at p. 10,206.

48. In 1987, the Federal Upper Limit program (FUL) was established for Medicaid.[49] This program was enacted to assure the Medicaid program a uniform price nationally for multisource drugs, and to limit reimbursement to the AWP of the lowest-priced therapeutically equivalent product.[50] While FULs could be implemented by CMS once three generic versions of the drug were on the market, the agency consciously chose not to implement FULs for injectable drugs like the ones at issue in this litigation. According to Sue Gaston, the Federal official responsible for implementing the FUL program, her agency, while aware of sometimes large differences between AWP and acquisition cost, formulated and maintained a policy not to implement FULs for injection drugs like the ones at issue here.[51] This policy continues to this day, as FULs are still not in place for these drugs.

49. A 1989 U.S. Senate staff report concluded,

> There are two markets in the U.S for most big selling prescription drugs: a price competitive market characterized by deep discounts off of list price, and a high-priced market, where retail customers, Medicare and Medicaid purchase their prescription drugs.[52]

The report also found that the Veterans' Administration received an average discount of 41 percent off AWP for single source drugs and 67 percent off of AWP for multiple source drugs. In the private sector, the report noted that hospitals, managed care entities

[49] Federal Register, "Part 447: Payments for Services" v. 52 n. 147 July 31, 1987 at 28557-28558.
[50] A FUL could be adopted for a multisource drug once there were three therapeutically equivalent products in the market. CMS website at http://www.cms.hhs.gov/Reimbursement/05_FederalUpperLimits.asp
[51] Deposition of Sue Gaston, January 24, 2008 at 244-252.
[52] United States Senate, Special Committee on Aging, "Prescription Drug Prices: Are We Getting Our Money's Worth?" August, 1989 at 3.

and nursing home that have contracts with wholesalers receive discounts of up to 99 percent off of AWP.[53]

50. An OIG report in 1992 indicated the difference between AWP and acquisition cost. The report fount this difference ranges from 12 percent to 83 percent for the most common chemotherapy drugs.[54] The report stated that "AWP is not a reliable indicator of physician cost; indeed *Red Book* officials confirmed that AWP is not designed to reflect physicians' costs."[55] The OIG concluded, "…there is no single discount rate which can be applied to the AWP to provide a reasonably consistent estimate of physician's acquisition cost."[56]

51. In the 1992 OIG report on dialysis drugs, it was reported that a 500mg unit of vancomycin was being purchased by dialysis centers at prices ranging from $3.45 up to $26.61. The $26.61 figure is some 39 percent above the then-current AWP of $19.17. The OIG estimated acquisition cost based on surveys of dialysis centers, and recommended that vancomycin be reimbursed at $5.00.[57]

52. The current action was filed in 1995. The complaint details as part of the allegations the difference between AWP and acquisition cost, and gives numerous examples involving the drugs at issue in this litigation.[58] These examples quantify exactly the information the Government claims that CMS and state agencies lacked—the existence and size of spreads between AWP and provider acquisition cost.

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[53] Id. at 11.
[54] U.S. HHS Office of Inspector General, "Physicians' Costs for Chemotherapy Drugs," November, 1992 at Appendix 3
[55] Id. at 5
[56] Id. at Appendix 2
[57] U.S. HHS Office of Inspector General, "Cost of Dialysis-Related Drugs," October, 1992 at 9, 15.
[58] Complaint at Exh. 1.

53. A lengthy article on the divergence between AWP and acquisition costs appeared in the June 10, 1997 issue of *Barron's* newspaper. Entitled "Hooked on Drugs," the article found acquisition costs for multisource drugs 60 to 85 percent below AWP.[59] The *Barron's* survey included vancomycin, one of the drugs at issue here. This article was quoted in the 1997 OIG report on generic drug pricing.[60]

54. The relator in this matter, Ven-a-Care, invited states to a meeting in September 1995 to encourage state AGs to initiate litigation parallel to the Federal action. The acquisition costs for the drugs at issue in this litigation were discussed in detail at this meeting. The state AGs and the Justice Department were provided with specific information about the actual acquisition costs for the subject drugs at this meeting.[61]

55. In 1997 the OIG conducted a study based upon invoices collected from pharmacies with the stated purpose of calculating the difference between AWP and actual acquisition costs. The OIG concluded "we have determined that there is a significant difference between pharmacy acquisition cost and AWP."[62]

56. Also in 1997, the OIG reported that "Medicare allowed between 2 and 10 times the actual average wholesale prices…"[63] Subsequent to this report, President Clinton addressed Medicare and Medicaid reimbursement in his radio address in December 1997,

> Sometimes the waste and abuses aren't even illegal; they're just embedded in the practices of the system… These overpayments occur because Medicare reimburses doctors according to the published average

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[59] Barron's Newspaper, "Hooked on Drugs" June 10, 1997.
[60] U.S. HHS, Office of the Inspector General, "Medicaid Pharmacy—Actual Acquisition Cost of Generic Prescription Drug Products," August, 1997 at 1-2.
[61] Gaston Deposition at 98 and Abbott Exh 453.
[62] U.S. HHS Office of Inspector General, "Medicaid Pharmacy—Actual Acquisition Cost of Generic Drug Products," August, 1997 at 5.
[63] OIG, "Excessive Medicare Payments…," supra note 29 at 8.

> wholesale price, the so-called sticker price for drugs. Few doctors actually pay the full sticker price. In fact, some pay just one-tenth…[64]

b. State Medicaid Officials' Testimony

57. In the 14 years since the filing of this action, in deposition and trial testimony in this and related matters, state and federal officials have spoken to the extensive knowledge at various levels of HCFA (later CMS) and state agencies that AWP was not a sales price. I note that Dr. Duggan has testified that he has reviewed none of this testimony from state Medicaid officials, despite its obvious relevance to the matter at hand.[65]

58. For example, a Florida Medicaid official testified that he knew by as early as 1987 that "everyone gets a discount" from AWP,[66] and by 1990 knew that AWP was not a "reasonable indicator" of sales price for generic drugs.[67] In Ohio, Robert Reid of the Department of Human Services testified that he was aware that "nobody paid AWP" going back to 1969, and that the differences between AWP and acquisition cost varied greatly by drug.[68] In Delaware, a 1996 study showed pharmacies purchasing generic drugs at an average discount from AWP of over 60 percent.[69] A representative from New Jersey Medicaid testified that

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[64] President William Clinton, Radio Address 12/13/97, John T. Woolley and Gerhard Peters, *The American Presidency Project* [online]. Santa Barbara, CA: University of California (hosted), Gerhard Peters (database). Available from World Wide Web: http://www.presidency.ucsb.edu/ws/?pid=53703.
[65] Duggan Deposition at 679-680.
[66] Deposition of Jerry Wells, Florida State Medicaid, December 15, 2008 at 69-70.
[67] Id. at 340.
[68] Deposition of Robert Reid, Ohio Department of Job and Family Services, December 15, 2008 at 101-104.
[69] Deposition of Cynthia Danemark, Delaware Division of Medicaid and Medical Assistance, December 9, 2008 at 142-145. Ms. Danemark also testified that she did not think there was any predictable relationship between AWP and acquisition cost in her

> New Jersey, the state, has always had an understanding of what AWP was. We didn't operate within a vacuum. There were always ongoing discussions, and…going back to the '90s there were ques – even back in the '80s there were questions regarding AWP, its value with respect to establishing a benchmark for reimbursement.[70]

59. I have found similar references in the deposition testimony of at least nine other state officials,[71] all testifying to the fact that it was known in their particular state agencies that AWP was only a starting place for negotiations, that discounts, sometimes deep discounts from AWP were common. Several of these officials spoke of their awareness of these facts in the context of trying to change reimbursement systems, and/or reasons why they decided against such changes.

60. The accounting firm of Myers & Stauffer conducted studies of drug acquisition costs in the Medicaid program on behalf of both state Medicaid agencies and the Office of the Inspector General of the Department of Health and Human Services. Many state Medicaid agencies conducted these studies because, in the words of one such study conducted 22 years ago in Connecticut, "…the federal government is increasingly emphasizing controlling Medicaid costs by the use of more conservative estimates of

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experience. Id. at 269. She knew that AWP was not a valid basis for reimbursement back to 1988. Id. at 311-312.

[70] Deposition of Edward Vaccaro, New Jersey Department of Human Services, December 3, 2008 at 638.

[71] Deposition of Harry Sullivan, Director of Pharmacy Services, TennCare, March 12, 2008; Deposition of Kevin Gorospe, California Department of Human Services, March 19, 2008; Deposition of Cody Wiberg, Minnesota Department of Human Services, March 14, 2008; Deposition of Sandra Kramer, Michigan Medical Services Administration, March 25, 2008; Deposition of Gerry Dubberly, Georgia Department of Community Health, December 15, 2008; Deposition of Benny Ridout, North Carolina Department of Health and Human Services, December 5, 2008; Deposition of James Parker, Illinois Department of Healthcare and Human Services, November 18, 2008; Deposition of Jesse Anderson, Oregon Department of Human Services, December 16, 2008; Deposition of Mary Terrebonne, Louisiana Department of Health and Hospitals, November 7, 2008.

estimated acquisition cost."[72] Myers & Stauffer conducted around twenty such studies on pharmacy acquisition costs from 1987 to 2001, some covering multiple states. A summary of these studies shows that Myers & Stauffer found that for multisource drugs, there were discounts from AWP ranging from 41 percent to over 80 percent.[73] The commissioning of these studies indicates not only that many state Medicaid officials were aware of the divergence between AWP and pharmacy acquisition costs, but that they were also seeking to do something about it. I note that Dr. Duggan relied on Myers & Stauffer for support in understanding state Medicaid figures, but made no inquiries concerning the development or implementation of state reimbursement systems.[74]

61. Dr. Duggan's but-for world acknowledges none of this. He fails to state what his assumptions are regarding these factors. The U.S. DHEW first examined the issues with Medicaid reimbursements over 40 years ago. Over time the evidence shows that these issues were a subject of interest at many levels of government. State agencies had specific and detailed information from a number of sources that AWP was higher than the pharmacy acquisition cost for prescription drugs.

62. Dr. Duggan's damage calculations are predicated on a but-for world where the extant reimbursement method is the result of government ignorance, rather than deliberate government policy. Dr. Duggan's but-for world assumes that the Government

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[72] Myers & Stauffer, "A Survey of Costs of Dispensing Prescriptions and Estimated Acquisition costs in the State of Connecticut," February, 1987 at 53.
[73] Myers & Stauffer, "A Survey of Acquisition Costs of Pharmaceuticals in the Commonwealth of Kentucky," November, 2001 at Table B.1; Myers & Stauffer, "A Survey of Acquisition Costs of Pharmaceuticals in the State of Arkansas," June 2001 at Table B.1; See also "Pharmacy Final Reports Related to Dispensing and Acquisition Costs Produced by Myers and Stauffer," Exhibit 7, Deposition of Tracy Allan Hansen, December 10, 2008.
[74] Duggan Deposition at 680-685.

would have based reimbursements on his estimate of average acquisition cost once they learned that AWP was not equal to acquisition cost. Even a cursory examination of evidence over the past 40 years demonstrates that the government had copious information that AWP was not acquisition cost, yet the reimbursement method did not change.

63. A valid damage methodology in this matter would not simply assume government ignorance of the facts. A valid methodology would need to consider the information available to government officials at various points in time, acknowledge attempts to change the reimbursement method in light of this information, and why government agencies or the Congress rejected these alternatives. Dr. Duggan does none of this.

2. Dr. Duggan's Methodology Wrongly Focuses On Ingredient Costs In Isolation, Rather Than Focusing On The Total Reimbursement To Providers

64. Reimbursement methodologies varied by state and over time. One common model for Medicaid ingredient cost reimbursements to pharmacies during this period was to set reimbursement equal to the lesser of 1) AWP minus a percentage ("scaled AWP"); 2) the pharmacy's usual and customary charge (U&C); 3) the state maximum allowable charge (MAC); or 4) the federal upper limit price (FUL), if any. A dispensing fee is added to each of these ingredient cost reimbursements except U&C. The dispensing fee is intended to cover all of the pharmacy's costs, including the cost of storing, preparing, delivering and administering the prescription.

65. It was widely reported that the actual cost of filling a prescription at a pharmacy generally exceeded the Medicaid dispensing fees. The inadequacy of dispensing fees was especially evident for the drugs at issue in this litigation. These injectable drugs must be

stored in controlled conditions to maintain sterility and stability, and compounded in a sterile environment requiring the use of specialized equipment. These drugs are not self-administered, but require the services of a trained professional to ensure the right dose is administered on the right schedule and that the proper infusion device is used and used or installed correctly. Professional services are also needed to flush the infusion system properly between doses, and to monitor the patient for adverse reactions.[75]

66. The accounting firm of Myers and Stauffer conducted a total of 47 studies of dispensing fees, pharmacy dispensing costs and/or pharmacy acquisition costs between 1987 and 2007.[76] The Myers and Stauffer surveys showed that state Medicaid dispensing fees were often lower than the actual average costs of filling prescriptions in the states. Again, the Myers and Stauffer cost surveys were primarily focused on the costs of filling prescriptions for patient administered drugs—not infusion drugs like the ones at issue here which cost far more to compound, distribute and administer.

67. It is important to note that the Myers and Stauffer reports often explicitly recognized the fact that ingredient cost reimbursement above acquisition cost made up for deficiencies in the dispensing fee payments for both private and public payers. A June 2002 Myers & Stauffer report to the State of California found that,

> Findings from this study indicate that the current pharmacy ingredient reimbursement rate of AWP less 5% provides payments in excess of the costs actually incurred by California pharmacies in acquiring pharmaceutical products for Medi-Cal recipients. In fact, the acquisition cost study findings indicate that for a "typical" prescription, a pharmacy's margin on ingredient reimbursement is approximately $10. *These margins on ingredient cost must be considered in tandem with an analysis of*

[75] House Committee on Ways and Means, "Statement of the National Home Infusion Association," accessed online at http://waysandmeans.house.gov/hearings.asp?formmode=view&id=6334

[76] Deposition of Tracy Allen Hansen, 12/10/2008, at Exh. 7.

> *pharmacy dispensing cost and dispensing fee reimbursement in order to fully evaluate the issue of the adequacy of Medi-Cal pharmacy reimbursement*. [emphasis added][77]

A second 2002 report specifically on dispensing fees in California states,

> The Department's current pharmacy dispensing fee is below the average cost of dispensing prescriptions. This finding alone does not indicate that the current pharmacy reimbursement rates are inadequate since both dispensing and ingredient reimbursement rates should be considered in tandem.[78]

A Kentucky report noted that other third party payers used ingredient cost payments to make up for low dispensing fees.

> Dispensing fees paid by most third party payers are set at levels well below the dispensing cost of most pharmacies. Margins are still realized on third party prescriptions, however, due to the level of ingredient reimbursement.[79]

68. The drugs studied in the Myers and Stauffer papers were predominantly patient-administered pills and liquids. The discrepancy between dispensing fees and actual dispensing costs would be greater still for the physician-administered injectable drugs at issue here.[80]

69. These studies reported to state Medicaid agencies that dispensing fees were often inadequate to cover the costs of filing prescriptions. These reports also indicate that attempts to lower ingredient cost reimbursement by increasing the discount from AWP needed to be in the context of the resulting adequacy of the overall reimbursement.

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[77] "A Survey of Acquisition Costs of Pharmaceuticals in the State of California," Myers and Stauffer, June 2002 at 4-5.
[78] "A Study of Medi-Cal Pharmacy Reimbursement," Myers and Stauffer, June, 2002 at 6.
[79] "A Survey of Dispensing and Acquisition Costs of Pharmaceuticals in the Commonwealth of Kentucky, Myers and Stauffer, 2000 at 35.
[80] See Myers & Stauffer, "Study of Medi-Cal Pharmacy Reimbursement," at 59-62.

70. There is substantial testimony in this matter from many state Medicaid officials that they were aware that their dispensing fees were generally inadequate to compensate pharmacists for filling prescriptions generally, and for home infusion drugs in particular.[81] Officials testified that attempts to reduce reimbursements substantially would require increases in dispensing fees to compensate pharmacists. Cody Wiberg of the Minnesota Department of Human Services testified,

> …you have to understand that there's two sides of the equation, that the dispensing fees are kept artificially low. That if you just reduce the ingredient reimbursement to actual acquisition cost, and don't do anything with the dispensing fee, there's at least the possibility that you're going to have access problems for patients, because pharmacies at that point might drop out of the system.
>
> […]
>
> But if we move towards more transparency and we get closer to reimbursing on the ingredient side at what providers actually pay, then we have to look at the dispensing fee side in the case of pharmacies, because we've always kept that below what we think the true cost of dispensing is to make up for the fact that there is some money being made on the ingredient side. So to the extent, again, that you start paying people a dispensing fee or a total reimbursement that does not even get back the cost of the drugs, plus the cost of labor and the computer systems and the lights and all that, you could have providers…start dropping out of Medicaid.[82]

[81] State officials testifying about the inadequacy of dispensing fees include Sullivan Deposition, Director of Pharmacy Services, TennCare, supra. note 71; Gorospe Deposition California Department of Human Services, supra. note 71; Wiberg Deposition Minnesota Department of Human Services, supra. note 71; Dubberly Deposition, Georgia Department of Community Health, supra. note 71; Ridout Deposition, North Carolina Department of Health and Human Services, supra. note 71; Parker Deposition, Illinois Department of Healthcare and Human Services, supra. note 71; Terrebonne Deposition, Louisiana Department of Health and Hospitals, supra. note 71; Danemark Deposition, Delaware Division of Medicaid and Medical Assistance, supra. note 71; Vaccaro Deposition, New Jersey Department of Human Services, supra. note 71; and Wells Deposition, Florida State Medicaid, supra. note 71.

[82] Wiberg Deposition, supra. note 71 at 170-172.

71. Jerry Dubberly of Georgia testified that the fact dispensing fees were kept low because ingredient costs were high was not only a common practice of the states he had contact with, but also that this practice was well known to the Federal agencies, HCFA or later, CMS.[83]

72. Officials from other states testified that their payments were intentionally set to allow for a profit to be paid to providers. For example, Idaho's Medicaid statute mandates that pharmacy payments be based on the reasonable costs of filling prescriptions, and must also include a profit for providers.[84] Other states including Illinois[85], Oklahoma[86], and Tennessee[87] also sought to set payments so as to provide a profit to providers.[88]

73. In his analysis, Dr. Duggan assumes that nothing in the Medicaid reimbursement changes but the ingredient cost reimbursement. Despite overwhelming evidence to the contrary, he assumes that even if ingredient cost reimbursements were based on his estimate of average acquisition cost, pharmacies would continue to participate in the Medicaid programs, even if the extant dispensing fees are inadequate to cover costs. If dispensing fees are inadequate to cover the costs of compounding and administering the drugs at issue here, these same fees will be even less adequate when ingredient cost reimbursement is reduced to Dr. Duggan's version of average acquisition cost.

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[83] Dubberly Deposition, supra. note 71 at 384-386.
[84] Idaho Administrative Code, Agency 16.03.09.817.
[85] Parker Deposition at 137.
[86] Deposition of Nancy Nesser, Oklahoma Health Care Authority, December 12, 2008 at 60.
[87] Sullivan Deposition at 161.
[88] See, e.g., Danemark Depostion at 179:7-181:15; Parker Deposition at 137:13-21; Terrbonne Deposition at 216:5-217:4; Sullivan Deposition at 59:17-61:14, 62:13-63:3, 240:20-241:8; Wiberg Deposition at 67:15-69:21, 72:12-18, 183:17-186:12.

74. This assumption does not conform to reality. As an economist, it is clear to me that if the overall reimbursement (ingredient cost plus dispensing fee) does not cover the costs of filling prescriptions, these pharmacies will refuse to fill such prescriptions. Another Government expert acknowledges this basic economic point. Dr. Stephen Schondelmeyer, in his recent report on proposed reductions in Medi-Cal pharmacy reimbursements in California writes,

> If the payment method sets the prescription payment amount below the actual costs for either drug product cost, cost of dispensing and related additional costs, or both, then problems with Medicare [sic] beneficiary access to pharmacy services will occur.
>
> …Any reasonable pharmacy…would be unwilling to provide prescriptions when the total payment falls short of the total actual drug product costs and the costs of dispensing and other costs.[89]

75. Dr. Schondelmeyer recognizes what Dr. Duggan fails to grasp: the total payment for the prescription, regardless of what portion is ingredient cost and what portion is dispensing fee, must cover the pharmacy's costs, otherwise they will not participate in Medicaid. Despite copious evidence that existing dispensing fees do not cover the costs of storing, preparing and administering the drugs at issue in this matter, Dr. Duggan assumes that state Medicaid agencies can dramatically lower ingredient cost reimbursement to his version of average acquisition cost, and keep dispensing fees at their low, unremunerative levels with no effect at all on pharmacy viability or continued participation in Medicaid program.

3. There is No Evidence of Any State Medicaid Program Adopting a Reimbursement Method Resembling the Method Assumed By Dr. Duggan

[89] Stephen Schondelmeyer, "Impact of the 10 Percent Fee-for-Service Payment Reductions on Medi-Cal Beneficiaries and Pharmacies," June 3, 2008 at ii.

76. For all of the reports, testimony and other facts that Dr. Duggan ignores in constructing his version of the but-for world, the best test is to examine whether any state, in the decades since the alleged problems with the current reimbursement system were widely reported, has adopted a reimbursement system that resembles the system proposed by Dr. Duggan. If Dr. Duggan's proposed system were realistic, then we would expect the recent reimbursement changes enacted by the U.S. Congress to conform closely to what Dr. Duggan has proposed. While states and the federal government have modified reimbursement methods over the years, and major changes were enacted by Congress in 2005, Dr. Duggan has presented no evidence and no example, up to the present day, of a single state replacing the reimbursement system at issue here with one resembling his. Where states have lowered ingredient cost reimbursements and held dispensing fees constant, none have reduced ingredient cost reimbursements to an average acquisition cost calculated similarly to that of Dr. Duggan. In states that have substantially reduced ingredient cost reimbursements, such reductions have been accompanied by increases in dispensing fees.[90]

77. In fact, while it is clear from the record that for many years public reports have shown that AWP is not the same as acquisition cost, the reimbursement system at issue in this litigation continues to be used widely. To this day, states continue to use, and CMS continues to approve State Implementation Plans using the scaled AWP methodology.[91] Attempts to change the reimbursement method have been met with political resistance and legal actions by physician and pharmacy associations. In some states, injunctions

[90] For example, California lowered ingredient cost reimbursements from AWP - 10% in 2000 to AWP – 17% in 2004. However, dispensing fees were increased from $4.05 in 2000 to $7.25 in 2004.

[91] See note 26 supra.

have been granted blocking proposed changes that were more modest than the changes proposed by Dr. Duggan.[92]

78. At the Federal level, HCFA revised the Medicaid manual in 1989 to require states' EACs to include a "significant discount" from AWP. One year later, Congress imposed a moratorium on state changes to pharmacy reimbursement policies lasting from 1990 until December 31, 1994. Dr. Duggan ignores this moratorium in his damage calculations.

79. It is again instructive to compare Dr. Duggan's but-for world with the changes to the reimbursement method instituted by the Federal government. Congress enacted these changes in 2005 following extensive public discussion of the alleged shortcomings of the reimbursement system at issue here. If Dr. Duggan's vision of the but-for world is correct, we should expect it to closely resemble the new methods enacted by Congress. Again, it does not.

80. In 2005, Congress reformed the Medicaid reimbursement system as part of the Deficit Reduction Act (DRA). Congress established a new Federal Upper Limit (FUL) at 250% of the Average Manufacturer's Price (AMP) of the lowest cost therapeutically equivalent drug.[93] Generally, providers will be reimbursed at the lesser of this FUL, a

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[92] Independent Living Center of Southern California, Inc. et al. v. Sandra Shewry, Director of Department Health Care Services, State of California, n. 08-56061, July 11, 2008; Arkansas Pharmacist Association v. Patricia Harris, Secretary of United States Department of Health and Human Services, n. 79-1592, February 12, 1980; Florida Pharmacy Association v. Douglas M. Cook 4:97cv322-r September 3, 1998; American Society of Consultant Pharmacists v. Ann Palta, Director of Illinois Department of Public Aid and The Illinois Department of Public Aid, case no. 00c7821, February 27, 2001; Pennsylvania Pharmaceutical Association v. Department of Public Welfare of the Commonwealth of Pennsylvania, case no. 80-1790, July 9, 1982.

[93] U.S. DHHS, Centers for Medicare and Medicaid Services, "Implementation of the Deficit Reduction Act (DRA) of 2005" Medicaid Drug Rebate Program, release No. 144,

state MAC, if any, EAC, or the pharmacist's usual and customary charge (U&C). Providers also receive a dispensing fee for FUL, EAC or MAC reimbursements. As part of the implementation of this new FUL, states were directed to review the accompanying dispensing fees to assure their adequacy,

> [S]tates should reexamine and reevaluate the reasonableness of the dispensing fee paid as part of the pharmacy claim. If States adjust their payment methodologies to reflect the ingredient cost of the prescription drug, we suggest that they also reevaluate their dispensing fees to ensure that these fees are reasonable.[94]

81. The differences between the actual system enacted by Congress and Dr. Duggan's purported but-for reimbursement system are significant. Dr. Duggan calculates his version of average acquisition cost, which is different than the Federal AMP. He then adds 25 percent to this amount, to arrive at his but-for version of AWP. He assumes that a 25 percent markup is adequate to cover provider profit margin and any dispensing, delivery and administration costs not covered by the dispensing fee. Congress in reality enacted a markup of 250 percent, ten times that proposed by Dr. Duggan.[95] Second, Dr. Duggan's but-for reimbursement system does not allow dispensing fees to be adjusted to compensate providers for their actual costs of preparing, delivering and administering the drugs. Congress, again contrary to Dr. Duggan's assumption, expressly directed states to review their dispensing fees in light of the new FUL regulations to ensure their adequacy.

82. I note that this new FUL calculation, even with its 250 percent markup over AMP, has yet to be enacted. The National Association of Chain Drug Stores filed suit to block

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December 15, 2006 at 1. Accessed at http://www.cms.hhs.gov/DeficitReductionAct/Downloads/rel144.pdf.

[94] Id. at 2.

[95] When considering low-cost drugs like the products at issue here, it is important to think in dollars, not percentages. A 25% profit may sound adequate, but not when one considers that 25% of an AMP of $1.00 is only $0.25.

implementation of this change, arguing that the FUL calculation, despite being ten times higher than that envisioned by Dr. Duggan, remains inadequate to compensate pharmacies for their costs.[96]

83. Dr. Duggan has assumed a but-for world for Medicaid pharmaceutical reimbursements far lower than what Congress actually enacted. This assumption has caused Dr. Duggan's calculation of alleged damages to be grossly inflated compared to what they would be if he had used as a but-for world the reimbursement calculation for Medicaid actually enacted by the Congress. Exhibit 9 shows some examples of the difference between Dr. Duggan's calculation of the alleged overpayment under Medicaid, and the actual "overpayment" calculated as the difference between what Medicaid actually paid, and what it would have paid had the new DRA FUL calculation been in place earlier.[97] For products like the ones at issue here, Medicaid was paying less under the system at issue in this litigation compared to what they would pay today under the congressionally mandated FUL.

84. As another example, the Department of Justice provided an "alternative source" of AWP data for the drugs at issue here to the pricing compendia, which published them on May 1, 2000.[98] The DOJ encouraged Medicare and state Medicaid agencies to use

[96] National Association of Chain Drug Stores et al., v. United States Department of Human Services et al., Case: 1:07-cv-02017, November 7, 2007.
[97] I note that to this day, CMS has not implemented a FUL for the drugs at issue in this case, even though CMS has the authority to do so. See ¶48 supra.
[98] U.S. HCFA, "An Additional Source of Average Wholesale Price Data in Pricing Drugs and Biologicals Covered by the Medicare Program," Program Memorandum AB-00-86, dated September 8, 2000.

these lower substitute AWPs as the DOJ claimed their AWPs were a better measure of cost, as their data was derived from wholesaler prices.[99]

85. The reaction of the state Medicaid agencies was mixed. Exhibit 10 shows that some states did not adopt the DOJ prices at all, while other states adopted the DOJ prices as the basis for reimbursement, only to abandon them. At least one state, Utah, adopted the DOJ prices, but raised their dispensing fees at the same time. The fact that states did not universally adopt and maintain their use of the DOJ prices is further evidence that Dr. Duggan's world is not an accurate rendition of the but-for world.[100]

4. Dr. Duggan Ignores The Real World Consequences Of His Assumed But-For World

86. Had states adopted Dr. Duggan's proposed but-for reimbursement system based on his calculation of average acquisition cost and no change in dispensing fees, it is clear such reimbursements would not be remunerative for large numbers of pharmacies. If Dr. Duggan's but-for reimbursements are inadequate for pharmacies to cover their costs of acquiring and distributing the drugs, the pharmacies will stop participating in state Medicaid programs.[101]

87. In making his unrealistic and unsubstantiated assumptions about the but-for world, Dr. Duggan is assuming that state Medicaid officials were not attentive to the legal mandate to provide access to care for Medicaid clients by having an adequate pharmacy

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[99] Id.

[100] On the Medicare side, it is noteworthy that the DOJ prices were introduced in September 2000. By November 2000, CMS abandoned the DOJ prices, prohibiting its carriers from using any of the DOJ prices in setting reimbursements. CMS required that reimbursements continue to be based on the AWPs published in carriers' "usual source[s]." U.S. HCFA "Source of Average Wholesale Price Data in Pricing Drugs and Biologicals Covered by the Medicare Program," Program Memorandum AB-00-115, dated November 17, 2000.

[101] See text accompanying ¶70 and ¶74.

network commensurate to that available to the general public. There is substantial testimony in this matter from state Medicaid officials stating that providing such access was a mandate they took very seriously. These officials also testified how adoption of a reimbursement such as described by Dr. Duggan would jeopardize patient access to pharmacy services, and how such a restriction in pharmacy access would be unacceptable.

88. Dr. Duggan's but-for reimbursements would likely raise government expenditures for administering the drugs at issue in this case. His inadequate reimbursements would jeopardize the continued existence of chemotherapy infusion centers and home infusion services. Without adequate reimbursements to prepare, deliver and administer these drugs, these less expensive, more convenient services could not survive. As a result, Medicaid recipients would have no choice but to receive these infusion services in a hospital,[102] at much higher cost to the government.

5. Dr. Duggan's Damage Calculations Are Unscientific And Highly Speculative

89. Dr. Duggan's selects ten states out of fifty. For these ten states, he calculates an assumed but-for AWP equal to his estimate of average acquisition cost plus 25 percent. This but-for AWP is then scaled by whatever percentage discount was used in these states at a particular time to calculate a but-for reimbursement. He calculates damages by taking the difference between the his calculation of the actual reimbursement paid by that state and his assumed but-for reimbursement. He then uses the difference between the

[102] National Home Infusion Association, supra. note 72.

two reimbursements for his ten states to extrapolate what he claims the damage would be in the other 38 states he analyzes.[103]

90. First, Dr. Duggan introduces error into his estimates by extrapolating unnecessarily. CMS, the relevant government agency in this matter, should have access to all of the claims data for all of the state Medicaid programs. Dr. Duggan had the ability to directly conduct his alleged damage calculation using actual data from each of the state Medicaid programs. He chose instead to use actual claims data from only ten states, some with incomplete data across the relevant time period, and then to extrapolate damages to the other 38 states.[104] He offered no explanation for ignoring the actual claims data. By extrapolating in this way, he makes the baseless and untested assumption that the reimbursement systems and resulting reimbursements are the same between his exemplar states and the other 38. He provides no factual basis for such an assumption. He provides no statistical tests of the accuracy of his extrapolations. Dr. Duggan's use of out of sample extrapolation, instead of analyzing actual claims data, introduces needless error and uncertainty into his damage estimates.

91. Second, his ten "exemplar" states are chosen in an ad hoc and unscientific manner. He makes no attempt, and offers no evidence, that the ten states from which he extrapolates are in any way representative of the population of states. This shortcoming further reduces confidence in his extrapolations, as the states from which he is extrapolating are not a random sample of the population. Dr. Duggan claims in his initial

[103] Out of 51 states and the District of Columbia, he chooses ten exemplar states. He excludes Arizona and Ohio from his analysis. Indiana he treats as a special case, extrapolating its alleged damages solely based on Illinois.
[104] He extrapolates damages for Indiana from data from only one state, Illinois. Indiana is then included as one of his exemplar states.

that he chose twelve states accounting for approximately 70 percent of total reimbursements for these drugs.[105] His selection of these exemplar states is not random, and Dr. Duggan presents no evidence that it is.

92. Third, Dr. Duggan's extrapolations are simply mechanical exercises, paying no attention at all to the actual reimbursement system in any particular state. Dr. Duggan only manipulates the numbers in the data, paying scant attention to the circumstances of individual states and of individual claims. This mechanical methodology does not check the accuracy of the transaction entries, and does not reveal the basis of reimbursement. His method does not indicate whether any particular reimbursement was in fact based on AWP as opposed to some other non-AWP-based methodology, or whether his calculation of damages in fact made sense for any particular state. Without such inquiries, Dr. Duggan cannot even tell whether any particular transaction was actually affected by the alleged AWP manipulation, that is, whether Abbott should even be liable on a particular claim under the Government's theory.

93. His dropping of Ohio from his analysis is another example of the ad hoc nature of Dr. Duggan's selection of exemplar states. Ohio was a low-reimbursement MAC state contained in his set of exemplars. Eliminating Ohio from the set of exemplar states caused total damages extrapolated to the other 38 states to rise. The reason, of course, is that eliminating low-damage Ohio raises the average damage calculated for the remaining exemplar states.[106] This higher average damage figure is then extrapolated to the other

[105] Duggan Report at 76.

[106] An obvious question is why Dr. Duggan did not replace Ohio, which DOJ dropped from the complaint, with another low cost state. Whether Ohio is contained in the Government complaint is irrelevant to whether it is representative of other states for purposes of extrapolation. As an alternative, Dr. Duggan is very familiar with Texas,

38 states. This situation clearly shows that Dr. Duggan's damage methodology is very susceptible to manipulation, as nationwide damage estimates may be raised or lowered by the judicious choice of particular exemplar states.

94. Dr. Duggan also makes no attempt to assess the information available or to address these issues in particular states to determine whether Medicaid transactions were in fact affected by the alleged AWP manipulation, or inconsistent with state policy. Evidence in the record indicates that officials in many states were quite knowledgeable about the facts of drug pricing, and were actively forming reimbursement policies in light of that knowledge. Dr. Duggan ignores the realities of state reimbursement policies, and assumes without basis that all states sought to set reimbursement equal to acquisition cost, regardless of the consequences to provider solvency and patient access.

95. To contain drug spending, some states adopted Maximum Allowable Cost (MAC) rules for a wide range of multisource drugs, including the drugs at issue in this case. MAC prices are generally the result of negotiation between the state Medicaid agency and pharmacies. Given the goals of the MAC program, MAC prices are a good indicator of the lowest reimbursement mutually acceptable to providers and the state. Furthermore, MAC prices reflect state policy, and embody the state Medicaid agencies' balancing of the dual, but conflicting, mandates of cost containment and patient access.

96. Dr. Duggan's methodology ignores all of this relevant history. He labels these negotiated MAC prices as being too high and fraudulent, and assesses alleged damages each time a MAC price exceeds his but-for price. The fact that the state mandated maximum allowable cost, often negotiated in light of actual acquisition costs, lies above

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having served as plaintiff's expert in that state's AWP action, and Texas is another low-reimbursement state.

his assumed but for price, is taken as an indication of fraud, rather than as an indication of a state agency trying to control costs while assuring adequate access to its constituents.

97. Other states did not negotiate directly with providers to determine MAC prices, but rather simply adopted the MAC price list paid by a third party payer operating in the state. That a third party payer was conducting negotiations does not change the conclusion that Dr. Duggan should not have considered such transactions to be fraudulent. Third-party payers face exactly the same problem as Medicaid agencies, that is, to contain drug spending while paying reimbursements high enough to maintain an adequate network of providers to serve their insureds. That some states would economize on negotiation by adopting MAC prices negotiated by a private sector insurer with the same basic goals does not alter the conclusion that such MACs were the embodiment of a considered state policy, rather than a fraudulent reimbursement as Dr. Duggan apparently believes.

98. Dr. Duggan takes great pains to claim that his alleged damage estimates are conservative—that is, favor Abbott—at every juncture in his analysis. In my opinion, it is not conservative to introduce error into one's estimates by extrapolating where one can calculate alleged damages directly. It is not conservative to use a damage methodology so obviously susceptible to manipulation by judicious choice of exemplars. It is not conservative to base one's extrapolations on an unscientific, nonrandom and unrepresentative sample of the states, assuming away differences between his exemplar states and the other 38 states. It is not conservative to ignore the realities of state reimbursement policies, and instead base one's estimates on a but-for world that has not been adopted by a single state in the fifteen years since the filing of this matter. It is not

conservative to ignore well-considered state policies designed to contain costs and ensure access, and to label as fraudulent and wrongful drug reimbursements made under such state policies. In my opinion, such obvious omission of important institutional details renders Dr. Duggan's alleged damage estimates inaccurate and unreliable.

VI. Concluding Comments

99. For all of the foregoing reasons, it is my opinion that Dr. Duggan's estimates are flawed, inaccurate and unreliable.

I reserve my right to supplement my opinions at trial or as new information warrants.

Dated: March 6, 2009

James W. Hughes, Ph.D.